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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,989	11/06/2001	Jaime Simon	61350A	5337
109	7590	07/22/2004	EXAMINER	
THE DOW CHEMICAL COMPANY INTELLECTUAL PROPERTY SECTION P. O. BOX 1967 MIDLAND, MI 48641-1967			BERKO, RETFORD O	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,989	SIMON ET AL.	
	Examiner	Art Unit	
	Relford Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/2/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement: Applicant's amendment filed September 2, 2003 is acknowledged.

Status of Claims

a. The status of the claims is as follows:

The status of the claims is as follows:

Claim 3 is cancelled in view of applicant's amendment.

Claims 1, 2 and 4-27 are pending following applicant's amendment.

No new claims were added.

b. The text of those sections of title 35 U.S.C. not included in this office action can be found in a prior Office Action.

c. The rejection of claims 1, 2 and 4-27 under 35 USC 103(a) as being unpatentable over Imondi et al (US 4, 143, 130) in view of Hiler et al (US 6, 132, 706) has been withdrawn in view of applicant's arguments.

d. This Office Action contains New Grounds of Rejections.

New Grounds of Rejections:

Claim Rejections - 35 USC § 102

1. Claims 19-25 remain rejected under 35 U.S.C. 102 (b) as anticipated by Samejima et al (EP 0077956).

The claims are directed toward a composition for removing fluid from the intestinal tract of a host comprising enteric-coated, non-systemic, non-toxic, water-absorbing polymer as active ingredient, wherein the water-absorbing polymer is capable of absorbing at least 10-40 its weight

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in physiological saline and wherein the polymer is a polysaccharide. The claims are also directed to the composition wherein the polymer is polyallyl amine; in bead form.

2. Samejima et al (Patent '956) teaches enteric-coated microcapsules comprising water-swallowable polymer material in the core, said polymer is capable of absorbing water (1.2 –1.5 times its weight; page 5, lin 22 to page 6, lin 9 and page 27, lin 1-5). Patent '956 teaches that the composition in granule formulation (page 22, lin 1-10). Patent '956 also teaches that the composition in the form of microcapsule, is capable of releasing the active component in the intestinal tract and maintain the core material in the stomach (page 2, lin 16-20).

3. Claims 19-25 are anticipated by Patent '956.

4. Claims 1, 7, 8, and 9 are rejected under 35 U.S.C. 102 (b) as anticipated by Thompson et al (US 5, 004, 603) and by Berger et al (US 4, 470, 975).

The claims are directed toward a method for removing fluid from the intestine of host by delivering effective amount of water-absorbent polymer to the intestinal tract wherein the polymer is capable of absorbing at least 10, 20 times its weight of physiological saline. The claims are also drawn toward the method wherein the polymer is formed by polymerization of monomers of acrylate or the polymer is made up of polymerized acrylic acid monomers or salts thereof or the polymer is a polysaccharide.

5. As in claim 1, 7, 8 and 9, Patent '603 teaches a method of administering a composition to ruminants, such feeding composition comprises of acrylic acid polymer that is capable of absorbing at least 10 times its weight of fluid at pH 7.0 (abstract and col 3, lin 35-60).

6. As in claims 1, 7-9; Patent '975 teaches a composition and method for removing fluid or edema from the gastrointestinal tract of an animal by administering to said animal dextran; a

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polysaccharide that is a polymer made of monomers of carbohydrate moieties (abstract, col 1, lin 55 and col 10, lin 5-30).

7. Claims 1, 7-9 are anticipated by Patent '603 and Patent '975.

Claim Rejections - 35 USC § 103

8. Claims 1-27 remain rejected under 35 U.S.C. 103(a) as unpatentable over Samejima et al (Patent '956) in view of Hilder et al (US 6, 132, 706) further in view of Berger et al et al (US 4, 470, 975).

The claims are drawn to a method for removing fluid from the intestine of host by delivering effective amount of water-absorbent polymer to the intestinal tract wherein the polymer is capable of absorbing at least 10 times its weight of physiological saline. The claims are also drawn toward the method of removing fluid wherein the polymer is a polysaccharide; wherein the enteric coating is methacrylic acid derivative or hydroxypropylmethylcellulose, methacrylic acid polymer; wherein the condition being treated is edema and wherein the polymer used is a polyallyl amine; and the polymer composition is in bead form.

9. We discussed previously in paragraph 2 that Samejima et al (Patent '956) discloses enteric-coated microcapsules comprising water-swellaable polymer material in the core. Patent '956 discloses a polymer is capable of absorbing water (1.2 –1.5 times its weight; page 5, lin 22 to page 6, lin 9 and page 27, lin 1-5). Patent '956 also discloses that the composition in granule formulation (page 22, lin 1-10). Patent '956 also discloses that the composition coated; is in the form of a microcapsule, and is capable of releasing the active component in the intestinal tract and maintain the core material in the stomach (page 2, lin 16-20).

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10. Patent does not disclose the use of polyallyl amine polymer and does not disclose the use of polysaccharide polymer in removing fluid or edema.

11. Hilder et al (Patent '706) discloses an invention wherein a polymer composition comprising polyallyl-guanidinium chloride is used for treating a patient with edema, by removing excess phosphate (found as a component of physiological saline) from blood. (abstract, col 5, lin 45-55 and col 11, lin 60-65). Patent '706 discloses oral administration of the polymer composition (col 12, lin 55-65).

12. Berger et al (Patent '975) discloses a composition and method for removing fluid or edema from the gastrointestinal tract of an animal by administering to said animal dextran; a polysaccharide that is a polymer made of monomers of carbohydrate moieties (abstract, col 1, lin 55 and col 10, lin 5-30).

13. One of ordinary skill in the art would be motivated to make a composition comprising of water absorbent polymer and use the composition in the form of tablet or capsule for treatment of excess fluid in the gastrointestinal tract and as a means for controlling phosphate in the body as in the cited art (e.g. Patent '706, abstract, col 3, lin 50 and col 4, lin 5-35). By coating the composition with enteric polymer, one of ordinary skill would expect to obtain an intact and therefore effective composition for removing excess fluid from the body---without the enteric coating, the polymer in the composition (e.g. polysaccharides) would be more susceptible to degradation by the acidic environment of the stomach (see Patent '975; col 4, lin 55-60 for the suggestion or motivation for enterically coating the composition). Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Response To Arguments

14. Applicant's arguments filed September 2, 2003 have been fully considered but they are not found persuasive.

15. First, Claims 1, 7, 8, and 9 are rejected under 35 U.S.C. 102 (b) as anticipated by Thompson et al (US 5, 004, 603) and by Berger et al (US 4, 470, 975). Second, Claims 1-27 remain rejected under 35 U.S.C. 103(a) as unpatentable over Samejima et al (Patent '956) in view of Hilder et al (US 6, 132, 706) further in view of Berger et al et al (US 4, 470, 975).

16. Applicants argue that the present invention is distinguished from the invention disclosed in the Samejima reference (Patent '956) in that the present invention is directed to the use of a water-absorbent polymer as the active ingredient while the water-absorbent polymer in Patent '956 is not the active material.

17. In response to this argument, Patent '956 discloses that the water-swellaable polymer material in the composition forms the core contained in the microcapsule and that it is the active component (page 2, lin 10-20).

18. Applicants argue that while the present invention claims that the composition is useful for removing fluid from the intestinal tract, that the present invention is distinguished from the invention disclosed in the Samejima reference (Patent '956), which does not teach or disclose any use for the composition.

19. In response, the scope of the disclosures in the Samejima reference (Patent '956) read on the claims of the present invention in that the claims of the present invention, when given the broadest interpretation, is a composition comprising enterically-coated polymer, thus permitting the addition of ingredients that may not necessarily be disclosed in the Patent '956. Furthermore,

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because applicant claim a composition, the disclosures in Patent '956 may read on applicant's claims for the composition, it is not necessary for the prior art reference to disclose the use for the composition.

Conclusion

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Retford Berko
Tel: 571-272-0590

